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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
LU,F

ART UNIT	PAPER NUMBER
1655	17

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/310,667	Ecker et al.,
Examiner	**Art Unit**
Frank Lu	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 9, 2001* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *27-29, 35-41, and 43-51* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *27-29, 35-41, and 43-51* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on July 30, 2001 has been entered as Paper No: 16. The claims pending in this application are claims 27-29, 35-41, and 43-51. Rejection and or objection not reiterated from the previous office action are hereby withdrawn. The following rejections are based on amendment.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 35-41 and 43-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note that claims 36-41 and 43-50 are dependent on claim 35.

Claims 35, 43, and 51 recite the limitation "said target nucleic acid" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

In page 6, second paragraph of applicant's remarks, applicant argued that claims were clear and definite since the phrase "said target nucleic acid" was replace by the phrase "RNA of a selected organism".

This arguments has been fully considered but it is not persuasive toward the withdrawal of the rejection because the phrase "said target nucleic acid" can still be found in line 10 of claim 35 and claim 43.

Claim Rejections - 35 U.S.C. § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 35-41 and 43-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams *et al.*,(Nucleic Acids Res. 22, 4660-4666, 1994).

Williams *et al.*, teach changes in the stem-loop at the 3' terminus of histone mRNA affects its nucleocytoplasmic transport and cytoplasmic regulation. They showed that a protein, the stem-loop binding protein (SLBP), could bind the 3' end of histone mRNA and proper stem-loop RNA-SLBP interactions were required for efficient nuclear-cytoplasmic transport and proper regulation of histone mRNA degradation (see abstract and right column in page 4460). The SLBP interaction site on the 3' end of histone mRNA could be considered as a molecular interaction site. Note that, although the molecular interaction site taught by Williams *et al.*, was not identified by the method of claims 35-41 and 43-51, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."*In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Williams *et al.*, teach all the limitations recited by claims 35-41 and 43-51.

Response to Arguments

In page 3, last paragraph bridging to page 4, first paragraph of applicant's remarks, applicant argued that "the Williams reference does not anticipate claim 35" since it "is completely silent in regard to any methodology used to identifying a molecular interaction site".

This arguments has been fully considered but it is not persuasive toward the withdrawal of the rejection because claims 35 and 51 are directed to an oligonucleotide product, not a method. Even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself (see above).

7. Claims 27-29, 35-41, and 43-51 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Garcia *et al.,* (J. Mol. Biol. 254, 247-259, 1995).

Garcia *et al.,* teach solution structure of the ribosome-binding domain of *E. coli* translation initiation factor IF3. As acknowledged by Garcia, in prokaryotic organisms, the first step in the initiation of protein translation was the binding of the 3' region of the 16S ribosomal RNA to the complementary 'Shine & Dalgarno' sequence located a few bases upstream to the start codon of mRNA. This ensured a pre-positioning of the 30S ribosome (see page 247). Note that, although Garcia *et al.,* did not directly show to this interaction was specific for prokaryotic organisms as described claims 27, 35, and 51, this limitation is considered as inherent to the reference taught by Garcia *et al.*, since it has been well know that eucaryotes do not utilize this mRNA-rRNA base pair mechanism and 'Shine & Dalgarno' sequence has been only found in prokaryotic organisms (see Protein Synthesis in any Biochemistry Text Book, such as page 739 in Textbook of Biochemistry with clinical correlations, third edition, Edited by Thomas Devlin). Note it has been well know that the interaction between IF3 and 30S subunit of the ribosome is specific for prokaryotic organisms (see right column in page 248 and see Protein Synthesis in any

Biochemistry Text Book, such as page 739 in Textbook of Biochemistry with clinical correlations, third edition, Edited by Thomas Devlin). The interaction site of 16S RNA to mRNA that involved 'Shine & Dalgarno' sequence could be considered as a molecular interaction site Note that, although the molecular interaction site taught by Williams *et al.*, was not identified by the method of claims 35-41 and 43-51, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."*In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

In page 4, third paragraph of applicant's remarks, applicant argued that "the Garcia reference does not anticipate or render obvious claim 27-29 or 35" since it "fails to teach or suggest an oligonucleotide" and "is completely silent in regard to any methodology used to identifying a molecular interaction site".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, Garcia *et al.*, did teach or suggest the interaction site of 16S RNA to mRNA that involves 'Shine & Dalgarno' sequence because they described well known 'Shine & Dalgarno' sequence (page 247). Second, claims 27-29, 35-41, and 43-51 are directed to an oligonucleotide product, not a method. Even though product-by process claims are limited by and

defined by the process, the determination of the patentability of the product is based on the product itself (see above).

8. Claims 35-41 and 43-51 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ray Gutell (Nucleic Acids Res. 21, 3051-3054, 1993).

Ray Gutell teaches collection of small subunit (16S- and 16S-like) ribosomal RNA structure. In this study, they aligned 16S- and 16S-like ribosomal RNA sequence from different prokaryotic and eukaryotic organisms such as *E. coli* and *C. elegans* in 16S database and compared their second structure of (see left column in page 3054, Figure 1 in page 3052 and Figure 3 in page 3054). Note that, although Ray Gutell did not directly show a molecular interaction site in 16S- and 16S-like ribosomal RNA as described in claims 35 and 51, this limitation is considered as inherent to the reference taught by Ray Gutell since: (1) it has been well know that 16S- and 16S-like ribosomal RNA could interact with mRNA and modulated protein translation (see Protein Synthesis in any Biochemistry Text Book, such as page 739 in Textbook of Biochemistry with clinical correlations, third edition, Edited by Thomas Devlin). At least the interaction site of 16S RNA to mRNA that involved 'Shine & Dalgarno' sequence could be considered as a molecular interaction site (see above). Note that, although the molecular interaction site taught by Williams *et al.*, was not identified by the method of claims 35-41 and 43-51, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself.

The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."*In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

In page 5, first paragraph of applicant's remarks, applicant argued that "the Gutell fails to teach or suggest an oligonucleotide" and " there is also no teaching or suggestion in the Gutell reference of methodology used to identifying a molecular interaction site".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, 16S- and 16S-like ribosomal RNA sequence from different prokaryotic organisms disclosed by Gutell *et al.*, at least taught or suggested the interaction site of 16S RNA to mRNA that involved 'Shine & Dalgarno' sequence and this interaction site was well known in the art. Second, claims 35-41 and 43-51 are directed to an oligonucleotide product, not a method. Even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself (see above).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
September 7, 2001

Ethan Whisenant, Ph.D.
Primary Examiner (FSA)